UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | | |
|-----------------|-----------------------------------|----------------------|---------------------|------------------|--|--|
| 10/559,745 | 12/07/2005 | Takayoshi Mamine | 09812.0120-00000 | 5942 | | |
| | 7590 06/23/200 ENDERSON, FARAE | EXAMINER | | | | |
| LLP | ŕ | YU, MELANIE J | | | | |
| | RK AVENUE, NW N, DC 20001-4413 | | ART UNIT | PAPER NUMBER | | |
| | | | 1641 | | | |
| | | | | | | |
| | | MAIL DATE | DELIVERY MODE | | | |
| | | 06/23/2009 | PAPER | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| Office Action Communication | | Δ | Application No. Applicant(s) | | | | | | |
|---|---|--|---|---|--|-------------|--|--|--|
| | | | 10/559,745 | MA | MAMINE ET AL. | | | | |
| Office Action Summary | | | xaminer | Ar | t Unit | | | | |
| | | N | IELANIE YU | 16 | 41 | | | | |
| Period fo | The MAILING DATE of this commur r Reply | nication appea | rs on the cover shee | et with the corre | espondence ad | ldress | | | |
| WHIC - Exter after - If NO - Failu Any r | ORTENED STATUTORY PERIOD F CHEVER IS LONGER, FROM THE IN Insions of time may be available under the provisions SIX (6) MONTHS from the mailing date of this common period for reply is specified above, the maximum signer to reply within the set or extended period for reply eply received by the Office later than three months and patent term adjustment. See 37 CFR 1.704(b). | MAILING DAT s of 37 CFR 1.136(a munication. tatutory period will a v will, by statute, can | E OF THIS COMMU a). In no event, however, ma apply and will expire SIX (6) use the application to become | JNICATION. ay a reply be timely find the none ABANDONED (35) | iled nailing date of this o 5 U.S.C. § 133). | | | | |
| Status | | | | | | | | | |
| 1)[\] | Responsive to communication(s) file | ed on 21 Anril | 2009 | | | | | | |
| · | | | ction is non-final. | | | | | | |
| ′= | | <i>′</i> — | | natters prosec | cution as to the | e merits is | | | |
| ٥/ك | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | | | | |
| Dispositi | on of Claims | | | | | | | | |
| | | the annlication | nn . | | | | | | |
| • | Claim(s) <u>1-5 and 8</u> is/are pending in the application. 4a) Of the above claim(s) 1-3 and 8 is/are withdrawn from consideration. | | | | | | | | |
| | 4a) Of the above claim(s) <u>1-3 and 8</u> is/are withdrawn from consideration. | | | | | | | | |
| · | 5)∭ Claim(s) is/are allowed. 6)⊠ Claim(s) <u>4 and 5</u> is/are rejected. | | | | | | | | |
| · · | Claim(s) <u>4 and o</u> is/are rejected. Claim(s) is/are objected to. | | | | | | | | |
| • | Claim(s) are subject to restrict | rtion and/or e | lection requirement | | | | | | |
| 0)[| Claim(3) are subject to resum | ction and/or e | ection requirement. | • | | | | | |
| Applicati | on Papers | | | | | | | | |
| 9) 🗌 🤈 | The specification is objected to by th | e Examiner. | | | | | | | |
| 10)🛛 | 10)⊠ The drawing(s) filed on <u>07 December 2005</u> is/are: a)⊠ accepted or b)⊡ objected to by the Examiner. | | | | | | | | |
| | Applicant may not request that any obje | ction to the dra | wing(s) be held in abo | eyance. See 37 | CFR 1.85(a). | | | | |
| | Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | | | |
| 11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | | | | |
| Priority u | ınder 35 U.S.C. § 119 | | | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | | | | |
| 2) Notic 3) Inforr | e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (Fination Disclosure Statement(s) (PTO/SB/08) r No(s)/Mail Date | PTO-948) | Paper 5) Notice | ew Summary (PT0 No(s)/Mail Date of Informal Paten | · | | | | |

Application/Control Number: 10/559,745 Page 2

Art Unit: 1641

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 21 April 2009 has been entered.

Claim Rejections - 35 USC § 103

2. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheppard, Jr, et al. (US 6,143,247) in view of Virtanen (US 2001/0016316).

Sheppard, Jr. et al. teach a bioassay apparatus for performing bioassay comprising:

a substrate holder for holding and rotationally driving a substrate (platform, col. 10, lines 15-18) for bioassay (col. 5, lines 43-53; col. 13, lines 10-18), the substrate including:

a reaction region formed on an upper layer of the substrate (platform provided with wells that comprise specific binding reagents, specific binding reagents are in the well which is on the upper surface of the substrate and therefore forms an upper layer, col. 10, lines 32-39; col. 8, lines 12-14; reaction region 11 is on upper layer of substrate 14, Fig. 1D), and

Art Unit: 1641

an information region formed on a lower layer of the substrate (pits formed onto lower surface of substrate with lower layer of reflective coating, col. 8, lines 11-12; col. 11, lines 53-60; reflective material 15 on substrate 14, Fig. 1D),

wherein the reaction region is adapted so that a sample material and a fluorescence marking agent are permitted to be dropped from an upper side of the substrate (sample input 21 is facing upper side of the substrate, Fig. 2; col. 12, lines 52-67) and serving as a field of mutual reaction between the probe material and the sample material (reaction region has probe material that reacts with the sample, col. 18, lines 31-65),

and the reaction region receiving a laser beam with respect to the fluorescence marking agent from a lower side of the substrate (light source on bottom side of platform, col. 21, lines 47-56; light source 54 on bottom side of platform 52, Fig. 5D) and the information region receiving light from a lower side of the substrate to record and reproduce information contained in the information region (light source on bottom side of platform, col. 21, lines 47-56; elements for reading information region includes a light and is on bottom side of platform 52, Fig. 5D; col. 14, lines 56-67),

wherein the lower layer is spaced from the upper layer in a thickness direction by at least a depth of focus of the laser beam (upper layer and reflective lower layer are spaced apart by substrate, col. 11, lines 53-60; reflective material 15 is lower layer, upper layer 11 is reaction region and substrate 14 is the spacer in the thickness direction between the upper and lower layers, Fig. 1D; fluorescent signal is transmitted

through the substrate as seen in Fig. 5D and therefore the thickness of the substrate is a thickness that is at least a depth of focus of the fluorescence);

a fluorescence detection optical system for irradiating the laser beam having a first wavelength with respect to the reaction region of the substrate to detect the fluorescence having the first wavelength produced from the fluorescence marking agent in accordance with the fluorescence (col. 14, lines 31-55; fluorescent markers are detected, col. 22, lines 48-67; col. 32, lines 52-67; fluorescence and information reading/producing optical system are separate, col. 21, line 57-col. 22, line 47, therefore the fluorescence light system operates at a first wavelength, col.12, lines 15-35); and

an information recording/reproducing optical system for irradiating the light having a second wavelength with respect to the information region of the substrate (col. 14, lines 56-67; fluorescence and information reading/producing optical system are separate, col. 21, line 57-col. 22, line 47, and therefore the information recording/reproducing system operates at a second wavelength, col.12, lines 15-35).

Sheppard, Jr. et al. fail to teach a separate information recording/reproducing optical system for irradiating the light having a second wavelength.

Virtanen teaches a bioassaying apparatus comprising a substrate holder for holding and rotationally driving a substrate for a bioassay (par. 25), the substrate comprising a reaction region and an information region (data layer, par. 22 and Fig. 11C; and assay regions, par. 85-86 and Fig. 11D);

a fluorescence detection optical system for irradiating using a laser beam having a first wavelength with respect to the reaction region of the substrate (disk is scanned

with a laser reader to detect the presence of labels, par. 130) to detect a fluorescent label (par. 167); and

an information recording/reproducing optical system for irradiating light having a second wavelength with respect to the information region of the substrate (information recorded using recording laser at preselected wavelength, which is separate from the reading laser that detects fluorescence and also emits a wavelength that is dependent than that of the reading laser, par. 164), in order to selectively melt pits into the substrate to write data to the disk.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to use in the device of Sheppard, Jr. et al., a first fluorescence detection optical system that has a laser beam that generates a first wavelength for fluorescing a material and a second information recording/reproducing optical system for irradiating a light having a second wavelength with respect to the information region of the substrate as taught by Virtanen, in order to write data to a disk and provide detection of an assay without the need to change laser wavelengths during use.

With respect to claim 5, Sheppard, Jr. et al. teach the substrate being circular shaped (col. 10, lines 21-25) and the substrate holder rotationally driving the circular shaped substrate (col. 5, lines 43-53).

Response to Arguments

1. Applicant's arguments filed 21 April 2009 with respect to claims 4 and 5 have been considered but are moot in view of the new ground(s) of rejection. The previous

Art Unit: 1641

rejections of the claims have been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Virtanen teaching an two optical systems, wherein a first optical system comprises a laser beam used for fluorescence detection and the second optical system has a light source used for information/reproducing.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE YU whose telephone number is (571)272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Application/Control Number: 10/559,745 Page 7

Art Unit: 1641

/Melanie Yu/ Patent Examiner, Art Unit 1641